

Remarks

I. Support for the Amendments

By the foregoing amendments, new claims 59-92 are sought to be entered. Support for new claims 59-92 can be found, *inter alia*, in the specification at page 13, lines 15-26; at page 25, line 15, to page 26, line 26; at page 36, lines 7-28; at page 39, lines 13-15; and at page 39, line 28, to page 40, line 22. Accordingly, the foregoing amendments do not add new matter, and their entry and consideration are respectfully requested.

II. Status of the Claims

By the foregoing amendments, claims claim 57 and 58 have been cancelled without prejudice to or disclaimer of the subject matter encompassed thereby. Applicants reserve the right to prosecute the subject matter of these claims in one or more continuing applications. Also by the foregoing amendments, new claims 59-92 are sought to be entered. Upon entry of the foregoing amendments, claims 45, 49, 52-56 and 59-92 are pending in the application, with claims 45, 53, 59, 71 and 86 being the independent claims.

III. Summary of the Office Action

In the Office Action dated February 10, 2003, the Examiner has made two rejections of the claims. Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and objections and that they be withdrawn.

IV. The Rejection Under 35 U.S.C. § 112, Second Paragraph

In the Office Action at pages 2-3, the Examiner has rejected claims 57 and 58 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicants respectfully traverse this rejection.

In making this rejection, the Examiner contends that claims 57 and 58 are indefinite for reciting “working concentrations.” *See* Office Action at page 2, section 4, second paragraph. Applicants respectfully disagree with this contention, and respectfully assert that one of ordinary skill in the art would readily understand what is meant by a “working concentration” of a given composition for use in a given method, particularly since the concept of “working concentrations” is a term commonly used in the related arts. Moreover, the present specification provides non-limiting examples of the meaning of the phrase “working concentration,” in a variety of methods, a fact acknowledged by the Examiner in the present Office Action (*see* Office Action, sentence bridging pages 2-3). Accordingly, Applicants respectfully submit that a person of ordinary skill in the art would readily understand the meaning of the phrase “working concentration” as used in claims 57 and 58.

In any event, for reasons unrelated to this rejection and solely to expedite prosecution and allowance of the present application, claims 57 and 58 have been cancelled without prejudice or disclaimer. Hence, this rejection has been rendered moot.

V. The Rejection Under 35 U.S.C. § 103(a) Over Todd In View of Sobol and Isner

In the Office Action at pages 4-6, the Examiner has rejected claims 45, 49 and 52-58 under 35 U.S.C. § 103(a) as being unpatentable over Todd (WO 96/32500; Doc. “N1” cited on the Form PTO-892 attached to Paper No. 14; hereinafter “Todd”), in view of Sobol *et al.* (USPN 5,543,296; Doc. A1 cited on the Form PTO-892 attached to Paper No. 17; hereinafter “Sobol”) and Isner (USPN 5,652,225; Doc. B1 cited on the Form PTO-892 attached to Paper No. 17; hereinafter “Isner”). By the foregoing amendments, claims 57 and 58 have been cancelled, thus rendering moot the portion of this rejection that may have applied to those claims. Applicants respectfully traverse this rejection as it may be applied to the remaining claims.

In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *See In re Piasecki*, 223 USPQ 785, 787-88 (Fed. Cir. 1984). In order to establish a *prima facie* case of obviousness, all of the elements of the claims must be taught or suggested by the prior art. *See In re Royka*, 490 F.2d 981, 180 USPQ580 (CCPA 1974). Moreover, the Examiner can satisfy the requisite burden only by showing some objective teaching in the prior art, or that knowledge generally available to one of ordinary skill in the art, would lead that individual to combine the relevant teachings of the references in such a way as to produce the invention as claimed. *See In re Fine*, 5 USPQ2d 1596,1598 (Fed. Cir. 1988); *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). In the present case, the Examiner’s burden has not been satisfied since such a reason, suggestion, or motivation is lacking in the cited references. Absent such suggestion and motivation, the references may not be properly combined to render the claimed invention obvious. *See id.* Moreover, the teaching or

suggestion required to properly combine the disclosures of cited references must be found in the prior art itself, not in an Applicant's disclosure. *See In re Vaeck* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In view of these legal prerequisites under § 103, Applicants respectfully assert that a *prima facie* case of obviousness cannot be established with respect to the pending claims based on the cited references.

Todd discloses preparations for nucleic acid amplification by PCR (*see, e.g.,* Todd at page 22). As one of ordinary skill would have appreciated, however, Todd fails to disclose a composition that does not contain any nucleic acid molecules, since all of the compositions disclosed in Todd necessarily contain nucleic acid molecules. Moreover, Todd does not disclose the use of "master mixes" for any purpose. Hence, Todd is seriously deficient as a primary reference upon which to base a *prima facie* case of obviousness. These deficiencies in Todd are not cured by the disclosures of the remaining references cited by the Examiner in making this rejection.

First, Sobol does not disclose the preparation and use of compositions comprising a restriction endonuclease. Accordingly, Todd in combination with Sobol does not disclose or suggest a composition meeting the requirements of the claims.

Second, Isner does not provide the disclosure missing from the combination of Todd and Sobol: Although the Examiner asserts that Isner discloses the use of master mixes in the preparation of enzymatic reaction mixtures to provide "greater accuracy and reproducibility" (see Office Action at page 5, lines 6-8), Isner does not specifically disclose what reagents are included in the "master mixes." Hence, one of ordinary skill could have found no disclosure in Isner that would have been sufficient to provide the missing components from the compositions of Todd and Sobol, alone or in combination.

Accordingly, Isner fails to correct the deficiencies of Todd and Sobol.

In addition, Applicants respectfully assert that the Examiner has failed to show that a person of ordinary skill in the art would have been motivated to prepare the presently claimed compositions based solely on information contained within the cited references. In fact, the references cited by the Examiner relating to “master mixes” have nothing to do with, and do not include, restriction endonucleases. Therefore, the art teaches away from the combination of a restriction endonuclease in a master mix format. Accordingly, Applicants respectfully assert that a *prima facie* case of obviousness cannot be established with respect to applicants claims. Applicants therefore respectfully request that the rejection under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

VI. Conclusion

All of the stated grounds of rejection have been properly traversed or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn.

Applicants believe that a full and complete reply has been made to the outstanding Office Action and that, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Brian J. Del Buono", with a long horizontal flourish extending to the right.

Brian J. Del Buono
Attorney for Applicants
Registration No. 42,473

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1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600
165354.1